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Please replace claim 4 with the following amended claim:

4. (Amended) The stent delivery system of claim 1, the medical balloon further comprising:

A 2
a first cone, the first cone being immediately adjacent to the first end portion, the first cone having a first waist, the first waist having a first waist diameter, the first waist engaged to a first portion of the catheter shaft, the first end portion diameter being greater than the first waist diameter; and

a second cone, the second cone being immediately adjacent to the second end portion, the second cone having a second waist, the second waist having a second waist diameter, the second waist engaged to a second portion of the catheter shaft, the second end portion diameter being greater than the second waist diameter.

REMARKS

This Amendment is in response to the Office Action mailed August 28, 2002 wherein pending claims 1-21 were objected to and/or rejected to.

The specific objections/rejections to the claims are addressed in the following paragraphs, which have paragraph numbers and headings corresponding to those in the Office Action.

Claim Objections:

(1)

In the Office Action claim 4 was objected to for the informality wherein the word "send" in line 9 should read --second--. In response, Applicant has amended claim 4 to correct the informality.

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Claim Rejections 35 U.S.C. § 112:

(3)

In the Office Action claim 4 was rejected under §112 as being indefinite. Specifically, the Office Action indicates that it is unclear which "second end portion" is being referred to in claim 4.

In response Applicant asserts that each use of the phrase "second end portion" is both clear and definite. The instant claim recites "a second portion of the catheter shaft" but in regard to the catheter itself there is no reference to "a second end portion" of the catheter. As to the use of the phrase "second end portion", the first instance of "second end portion" is on lines 6 and 7 of claim 4 and properly claims antecedent basis from claim 1. The other recitation of the phrase "second end portion" occurs on line 9 of the claim within the phrase "the second end portion diameter". "The second end portion diameter" is an element clearly recited in claim 1 as well.

In light of the above, the rejection is respectfully traversed.

Claim Rejections - 35 U.S.C. § 102:

(4)

In the Office Action claims 1, 4, 6, 10 and 11 were rejected under §102(e) as being anticipated by U.S. 6,221,043 to Fischell et al (Fischell).

Initially it is noted that claim 1 is amended herein to clarify that it is the balloon which provides the unique configurations of the non-inflated and inflated states rather than an external force or object acting upon the balloon during inflation. The amendment to claim 1 contains no new matter and is fully supported by the Application as filed. Furthermore, the amendment is not believed to narrow the scope of the claim.

It is well settled that in order to anticipate a claim and render it invalid, a single prior art reference must expressly or inherently disclose each and every element as set forth in the claim. Constant v. Advanced Micro Devices, Inc., No. 88-1101, slip op. at 21 [7 USPQ2d 1057,

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1064] (Fed. Cir. June 9, 1988); Verdegaal Brothers, Inc. v. Union Oil Co., 814 F.2d 628, 631-33 [2 USPQ2d 1051, 1052-54] (Fed. Cir.), cert. denied, 108 S.Ct. 95 (1987); Structural Rubber Products Co. v. Park Rubber Co., 749 F.2d 707, 715-16 [223 USPQ 1264, 1270] (Fed. Cir. 1984). The prior art reference must also be enabling, placing the allegedly disclosed subject matter in the possession of the public. Constant, slip op. at 16 [7 USPQ2d at 1062-63]; Akzo N.V. v. United States International Trade Commission, 808 F.2d 1471, 1479 [1 USPQ2d 1241, 1245] (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987).

Fischell fails to teach a balloon having a middle portion diameter, a first end portion diameter and a second end portion diameter, wherein in the non-inflated state the middle portion diameter is greater than the first end portion diameter and the second end portion diameter, and in the inflated state the balloon provides the middle portion diameter with a diameter substantially the same as that of the fist end portion diameter and the second end portion diameter, as instant claim 1 describes.

When the balloon described in the Fischell reference is inflated, the balloon is provided with a configuration wherein the middle portion of the balloon body has a diameter greater than that of the adjacent end portions of the balloon body (see Fig. 4 as well as column 7, lines 36-39). However, when the balloon is inflated within a typical arterial stenosis as shown in FIG. 8, the shape of the stenosis constrains the balloon to provide it with the substantially cylindrical shape shown in FIG. 5 (column 7 lines 53-55, see also FIG. 2 and column 6 lines 11-17). In Fischell it is thus the shape of the stenosis, as shown in FIG. 8, rather than properties of the balloon, that provides the balloon with the substantially cylindrical configuration shown in FIG. 5.

The implicit requirement that the shape of a stenosis is necessary to provide the balloon with the desired substantially cylindrical shape is in contrast to the instant claims wherein it is stated that in the inflated state *the balloon*, rather than some external acting force, provides the middle portion diameter with a diameter substantially the same as that of the fist end portion diameter and the second end portion diameter.

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In light of the above, the rejection is respectfully overcome.

Claim Rejections - 35 U.S.C. §103

(6)

In the Office Action claims 2, 3, 7 and 9 were rejected under §103(a) as being obvious over Fischell.

More specifically, the Office Action indicates that it would have been obvious to manufacture the balloon of Fischell from the materials provided in instant claim 9, that it would have been obvious to utilize the balloon of Fischell to expand the middle portion of the stent before the end portions, and that when the balloon of Fischell is inflated "it would be obvious for the middle section with a larger diameter to expand relative to the side portions that have a smaller diameter creating an apex in the balloon at the middle portion with a stent conforming thereto."

In response, Applicant notes that Fischell fails to teach or suggest a stent delivery system having all of the elements of independent claim 1 of the present Application. More specifically, Fischell fails to teach or suggest a balloon wherein in the non-inflated state the middle portion diameter of the balloon is greater than the first end portion diameter and the second end portion diameter of the balloon, and in the inflated state the balloon provides the middle portion diameter with a diameter that is substantially the same as that of the first end portion diameter and the second end portion diameter. The additional elements asserted in the Office Action as being obvious in light of Fischell do nothing to address the failure of Fischell to teach or suggest all of the elements of instant claim 1.

In addition to the above, Fischell also fails to render claims 2, 3 and 7 obvious because in order for a reference or combination of references to render an application obvious, the reference(s) must be considered as a whole and suggest the desirability and thus the obviousness of making the combination (see Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462; 221 USPQ 481, 488 (Fed. Cir. 1984)).

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In specific regard the elements required in instant claim 2, there is nothing in Fischell that teaches or suggests that when the balloon is expanded the middle portion of the balloon pushes against the stent before the end portions as the instant claim describes. In addition, nowhere in Fischell is a suggestion or other motivation provided for to add such expansion characteristics to the balloon. Furthermore, by reciting that the greatest resistance to expansion is at a region around the balloon's and stent's longitudinal centers would seem to suggest that expansion of a middle portion of the balloon occurs after other portions of the balloon if at all (column 7, lines 51-53).

Regarding claim 3, Fischell fails to provide a specific illustration or any description of the balloon in the non-inflated state. Intuitively then, Fischell fails to teach or suggest a balloon having a middle portion whose diameter is greater than that of the end portions *in the non-inflated state* or to provide a specific range to which the diameter of the middle portion is greater than the diameter of the ends *in the non-inflated state*, as the instant claim recites. Because Fischell fails to teach or suggest any difference between the end portions of the balloon and the middle portion of the balloon *in the non-expanded state*, there can be no motivation to provide the range of difference stated in the instant claim.

Turning to the elements of claim 7, Fischell fails to teach or suggest that any portions of the stent are expanded before or after any other portions of the stent during expansion. Moreover, because the center of the stent is stated as being most resistant to expansion, it would seem that inherently the ends of the stent would expand before the center of the stent (column 7, lines 51-53). As a result, there is no motivation to provide the stent of Fischell with a stent center that is expanded before the first stent end and the second stent end as the present claim describes.

For the reasons stated above the rejection is respectfully overcome.

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(7)

In the Office Action claims 5 and 8 were rejected under §103(a) as being obvious over Fischell in view of U.S. 6,280,412 to "Penderson" [Pederson], Jr. et al (Pederson).

Initially, it must be noted that the proposed addition of Pederson does nothing to address the failure of Fischell alone to teach or suggest all of the elements of instant claim 1 from which claims 5 and 8 depend.

As indicated above, in order for a reference or combination of references to render an application obvious, the reference(s) must be considered as a whole and suggest the desirability and thus the obviousness of making the combination (see Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co., 730 F.2d 1452, 1462; 221 USPQ 481, 488 (Fed. Cir. 1984)).

In the present case there is no motivation or suggestion in the references as a whole to provide the balloon of Fischell with the sleeves of Pederson. In Fischell it is considered an "ideal configuration for deploying a stent" wherein the stent (30) is provided with zero balloon overhang (column 7, lines 36-39). That is, wherein the ends of the stent do not extend over the cones of the balloon. In Pederson however, balloon overhang appears to be an asset not only for unfolding the portions of the cones (32a and 32b) overlying the stent ends (36a and 36b), but also for aiding in retracting the sleeves (40 and 42) from the stent ends (36a and 36b) (see FIGs. 4, 9 and 10 as well as column 3, lines 7-19). It would be contrary to the stated ideal delivery configuration of Fischell to provide the balloon of Fischell with elements such as the sleeves of Pederson that would seemingly interfere with the ideal stent delivery configuration or require a less than ideal stent delivery configuration in which to function.

As a result there can be no motivation to combine the balloon of Fischell with the sleeves of Pederson.

It should also be noted that in attempting to establish a §103 obviousness rejection by combining two or more references, a prima facia case of obviousness has not been established if the intended purpose of one or both references is destroyed by their combination (In re Gordon,

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733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Assuming arguendo that motivation was found to combine the Fischell and Pederson references in the manner proposed in the Office Action, the addition of the Pederson sleeves to the Fischell balloon would interfere with the ability of Fischell to provide the ideal stent delivery configuration stated.

In light of the above the rejection is respectfully overcome.

(8)

In the Office Action claims 12-21 were rejected under §103 as being obvious over Pederson in view of U.S. 5,415,635 to Bagaoisan et al (Bagaoisan). The Office Action states that it would have been obvious to have provided the stent delivery system of Pederson with the balloon having first and second end portions with greater diameters than the middle portion of Bagaoisan, since the balloon having a middle portion with a smaller diameter than the end portions provides a balloon in the non-inflated state capable of conforming better to a patient's clogged passageways.

In order to provide the stent delivery system of Pederson with the balloon of Bagaoisan there must be some suggestion or motivation in the art as a whole to make the combination. Nothing in the art as a whole provides a suggestion or motivation to provide the stent delivery system of Pederson with a dilatation catheter balloon of Bagaoisan.

In order presently retain and deliver a stent, Pederson clearly describes a balloon (16) having folds (32a and 32b) which overlay the ends of the stent (36a and 36b) in a contracted state, but which open to release the stent (36) when the balloon (16) is expanded (column 2, lines 46-65). Bagaoisan on the other hand, describes a balloon having end sections (40 and 41) which function to secure the balloon on either side of the stenosis within a lumen (column 6, lines 38-40). The purposes of the sections (40 and 42) of Bagaoisan and the folds (32a and 32b) of Pederson have mutually exclusive functions. If a balloon of Bagaoisan were provided with the requisite stent retaining folds of Pederson, then the end sections (40 and 42) could not secure the balloon in place on each side of the stenosis, to which the stent is assumedly being delivered to.

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without impacting the stent against the vessel wall or interfering with the delivery of the stent by pinching the folds between the vessel and the yet undelivered stent.

Alternatively, if a stent were positioned in the reduced diameter middle portion (41) of a Bagaoisan type balloon, to allow any folds of the end portions (40 and 42) to open during expansion yet still be capable of securing the balloon within the lumen, then the balloon would fail to define a stent mounting region having the end portions which have diameters less than the middle portions as the instant claims require.

It is thus clear that if the stent delivery system of Pederson were provided with the balloon of Bagaoisan the function of either the Bagaoisan balloon and/or the Pederson system would be destroyed. As a result a §103 obviousness rejection cannot be established based on their proposed combination (*In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Due to the conflicting nature of the balloons described in Pederson and Bagaoisan, it is clear that the only motivation which exists to combine the references in the manner proposed in the Office Action is through the hindsight provided by the present Applications. The use of such hindsight is impermissible as the references must be viewed without the benefit of hindsight vision afforded by the claimed invention (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)).

In light of the above, the rejection is respectfully traversed.

FORMALITIES

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicant hereby petitions for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

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CONCLUSION

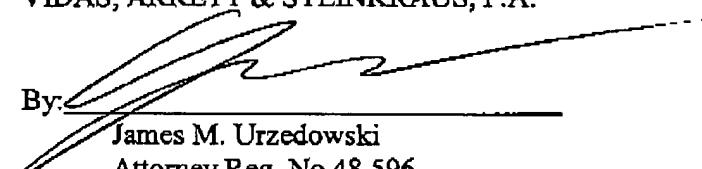
In view of the foregoing it is believed that the present application, with claims 1-21 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS, P.A.

Date:

11/25/02

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MARKED COPY OF THE AMENDED CLAIMS

Please replace claim 1 with the following amended claim:

1. A stent delivery system comprising:
 - a catheter, the catheter having a catheter shaft;
 - a medical balloon mounted on the catheter shaft, the medical balloon having a non-inflated state and being inflatable to an inflated state, the medical balloon having a stent mounting region, and a stent disposed about at least a portion of the stent mounting region, the stent mounting region having a middle portion, a first end portion adjacent to the middle portion and a second end portion adjacent to the middle portion, the middle portion having a middle portion diameter, the first end portion having a first end portion diameter, the second end portion having a second end portion diameter, in the non-inflated state the middle portion diameter being greater than the first end portion diameter and the second end portion diameter, in the inflated state the balloon providing the middle portion diameter with a diameter [being] substantially the same as that of the first end portion diameter and the second end portion diameter.

Please replace claim 4 with the following amended claim:

4. The stent delivery system of claim 1, the medical balloon further comprising:
 - a first cone, the first cone being immediately adjacent to the first end portion, the first cone having a first waist, the first waist having a first waist diameter, the first waist engaged to a first portion of the catheter shaft, the first end portion diameter being greater than the first waist diameter; and
 - a second cone, the second cone being immediately adjacent to the second end portion, the second cone having a second waist, the second waist having a second waist diameter, the second waist engaged to a second portion of the catheter shaft, the second end portion diameter being greater than the [send] second waist diameter.